UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,361	08/25/2003	Mark L. Weiss	13807.1USI1	2222

23535 7590 09/19/2007

MEDLEN & CARROLL, LLP
101 HOWARD STREET
SUITE 350
SAN FRANCISCO, CA 94105

EXAMINER	
TON, THAIAN N	

ART UNIT	PAPER NUMBER
1632	

MAIL DATE	DELIVERY MODE
09/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/647,361	WEISS ET AL.	
	Examiner	Art Unit	
	Thaian N. Ton	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,12,13,16-22,32-35 and 41-43* is/are pending in the application.

4a) Of the above claim(s) *14, 32 and 33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 12, 13, 16-22, 34, 35 and 41-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' Amendment to the claims, filed 5/29/07, is compliant and has been entered. Claims 4-11, 15, 23-31, 36-40 and 44-46 are cancelled; claims 1-3, 12, 13, 16-22, 32-35, 41-43 are pending; claims 14, 32 and 33 are withdrawn; claims 1-3, 12, 13, 16-22, 34, 35 and 41-43 are under current examination.

Election/Restrictions

Claims 14, 32 and 33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/14/06.

These claims were inadvertently left out of the restriction requirement, mailed 7/10/06. It is noted here that claim 14 is withdrawn, because it is directed to a method of differentiating stem cells, which requires different method steps than the instant claimed invention, which is directed to obtaining stem cells from umbilical cord matrix. Claim 32 is withdrawn because it is directed to transplanting the umbilical cord matrix cells, which requires different method steps, and technical considerations than the instant invention. Similarly, claim 33 is withdrawn because it is directed to a method of treating an animal for the alleviation of a disease symptom by transplanting the UCMS cell. Accordingly, each of these claims represents an independent method than that which has been instantly elected, and therefore, these claims have been withdrawn. The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include**

all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312. See also pages 7-8 of the Restriction Requirement, mailed 7/10/06.

Applicant's election without traverse of Group I (claims 1-3, 12, 13, 16-22, 34, 35 and 41-43) in the reply filed on 8/14/06 is acknowledged.

Color Drawings

Color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) is granted permitting their use as acceptable drawings. In the event that applicant wishes to use the drawings currently on file as acceptable drawings, a petition must be filed for acceptance of the color photographs or color drawings as acceptable drawings. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and an amendment to the first paragraph of the brief description of the drawings section of the specification which states:

> The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the U.S. Patent and Trademark Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

In the instant case, it appears that color drawings were filed with the instant application. Applicants are required to fulfill the requirements for color drawings as outlined above.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 12, 13, 16-22, 34, 35 and 41-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in view of the Wands factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention. The claims are directed to methods for obtaining stem cells from an umbilical cord matrix comprising fractionating the umbilical cord matrix source of cells, the source substantially free of cord blood, into a fraction enriched with stem cells, and a fraction depleted of stem cells and exposing the fraction enriched with stem cells to conditions suitable for cell proliferation. In further embodiments, the claims are directed to methods of generating a bank of umbilical cord stem cells.

Breadth of the claims. The claims are directed to umbilical cord matrix stem (UCMS) cells isolated from any animal source.

Guidance of the Specification/The Existence of Working Examples. The specification teaches the purification and isolation of umbilical cord matrix stem

(UCMS) cells (also known as Wharton's Jelly cells). The specification teaches that these matrix cells include extravascular cells, mucous-connective tissue (*e.g.*, Wharton's Jelly), but do not typically include cord blood cells or related cells. These cells include stem cells and other potentially useful cells, such as myofibroblasts. See page 8, lines 7-12.

The specification teaches methods of isolating UCMS cells by providing non-blood umbilical cord, adding cells from the tissue to a medium that contains factors that stimulate UCMS cell growth without differentiation. See pages 8-9, bridging ¶. The specification defines UCMS cells as pluripotent, lineage uncommitted cells that are capable of differentiating into cells from any of the three germ layers and germ cells; or a lineage-committed progeny cell that can eventually differentiate into any of the three germ layer derivatives or germ cells. See page 19.

The specification teaches the collection of Wharton's Jelly (p. 21), the isolation of UCMS cells (p. 22) and the establishment of UCMS cells in cell culture by fractionation of Wharton's Jelly into two fractions, one enriched for stem cells (p. 22).

The working examples of the specification teach the collection of umbilical cords and induction of neural cells from UCMS, wherein the cells were capable of forming cells that resembled neurons (p. 38 and Example 1). Example 3 teaches the characteristics of UCMS cells isolated from porcine and human Wharton's Jelly cells, in particular that the cells were examined for the expression of cKit, and it was found that cKit was highly expressed in Wharton's jelly colony-forming cells (see Figure 2), and that this expression decreased after differentiation of the cells into neural cells. Additionally, the cultures included colonies and cells that were positive for alkaline phosphatase and Oct4. See page 41, lines 15-18. It was also shown that Wharton's Jelly cells expressed telomerase activity that is about 10% of that expressed by a positive control carcinoma cell (p. 41, lines 3-25). The

specification additionally teaches that Wharton's Jelly cells contained smooth muscle actin-postivie myofibroblast-like stromal cells (p. 41, lines 30-31).

State of the Art/Predictability of the Art. The specification provides specific markers to define the claimed cells, such as cKit (CD117). See Figure 2. However, the presence of CD117 expression fails to provide sufficient teachings define the claimed cells. CD117 is a marker that is often expressed in hematopoietic stem cells, and also expressed in other cell types. For example, Went *et al.* (**J. Clin. Onco.**, 22(22):4514-4522) state the following, "KIT (CD117) is a transmembrane tyrosine kinase that acts as a receptor for mast cell growth factor (also known as stem cell factor or kit ligand). It belongs to the type III family of receptor kinases and can be detected in several normal cell types including hematopoietic cells, germ cells, interstitial cell of Cajal, ductal breast epithelium, mast cells, and melanocytes. KIT expression has been detected in a variety of different region of traumatic, hypoxic, or other disease state entities." See p. 4514, 1st column, 1st ¶.

The specification teaches that the cultures included colonies and cells that were positive for alkaline phosphatase and Oct-4. However, it appears that these cells were found in a heterogeneous population of cells, and it is unclear if these cells/colonies expressed both markers simultaneously. The state of art supports that Oct-4 is expressed in ES cells, but additionally, is expressed in other cell types. For example, Hochedlinger *et al.* (**Cell**, 121: 465-477 (May 6, 2005)) teach that, Oct-4, as well as other pluripotentcy-associated genes, are expressed in germ cell cancers. They state that this suggests that, "Primordial germ cells (PGCs) that usually express these genes may be the cells of origin in certain cancers of the gonads and (2) aberrant expression of Oct-4 may contribute to PGCs' malignant transformation." See p. 465, 2nd col., first full ¶.

Similarly, alkaline phosphatase is a marker that is expressed by pluripotent cells, however, the sole expression of this marker does not uniquely identify a specific cell type. For example, alkaline phosphatase activity is known to be present

in human EBs, although it decreased as the EB ages. Embryoid bodies (EBs) are formed when ES cells differentiate (Gerecht-Nir, **Developmental Dynamics**, 232: 487-497 (2005), page 488, col. 1, lines 2-20). When ES cells are permitted to form EBs, alkaline phosphatase remains relatively the same before decreasing (see page 490, Table 1). Thus, although Applicants have shown that their cells express alkaline phosphatase, this does not provide a definitive identification of one particular cell type.

The Amount of Experimentation Necessary. The specification teaches isolation of Wharton's Jelly cells. The specification uses the term Wharton's Jelly cells, and UCMS cells interchangeably (see p. 8, lines 7-8); however, the specification teaches that Wharton's Jelly contains various different subpopulation of cells, which can be fractionated (see, for example, p. 23, lines 7-10). Thus, it appears that UCMS cells are a subpopulation of Wharton's Jelly cells. However, the working examples in the specification do not differentiate between a composition of Wharton's Jelly cells, and UCMS cells of the instantly claimed invention. There is no purification step that appears to result in one cell type. It appears that the cells that are used in the working examples are heterogeneous populations of cells. Example 3 recites various markers that are expressed by Wharton's Jelly cells, (*e.g.*, cKit, Oct-4 and alkaline phosphatase) and additionally that the cells are composed of smooth actin-postive myofibroblast-stromal cells. Thus, it appears that the cells express markers that are expressed in hematopoietic cells, ES cells, as well as myofibroblast cells, and thus, can contain cells from various lineages, with various markers.

Claim 22 is not enabled, because it recites that the animal cells are bird cells. Birds do not form umbilical cords, the embryo is attached to a yolk sack by means of blood vessels, which are resorbed upon development. Additionally, birds form an allantois, which is resorbed by the growing chick embryo. Thus, it would appear that birds do not have umbilical cords, from which UCMS cells could be isolated.

Thus, it would have required one of skill in the art to practice undue experimentation to determine what type(s) of cells are encompassed by UCMS cells, because the markers that are identified to be expressed by the claimed cells are expressed in other cell types. Additionally, although the specification teaches various differentiation capacities of the cells, it is unclear whether the cells used are a heterogeneous, or homogenous population of cells. Thus, one of skill in the art would have had to practice undue experimentation to make the claimed cells, and further, because the cells have not been sufficiently characterized, would have had to practice undue experimentation with regard to how to use the cells in any of the contemplated uses.

Written Description

Claims 1-3, 12, 13, 16-22, 34, 35 and 41-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that, "[A]pplicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." *Vas-Cath Inc. v. Mahurkar,* 19USPQ2d at 1117. The specification does not, "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." *Vas-cath Inc. v. Mahurkar*, 19USPQ2d at 1116.

The claims are directed to methods for obtaining stem cells from umbilical cord matrix by fractionation. The specification teaches that the source from which the cells are isolated is from Wharton's Jelly. However, the specification fails to provide sufficient written description for the stem cells, as instantly claimed. For

example, the specification teaches that Wharton's Jelly contains various different subpopulation of cells, which can be fractionated (see, for example, p. 23, lines 7-10). Thus, it would appears that UCMS cells are a subpopulation of Wharton's Jelly cells. However, the working examples in the specification do not differentiate between a composition of Wharton's Jelly cells, and isolated UCMS cells of the instantly claimed invention. It appears that the cells that are used in the working examples are heterogeneous populations of cells. Example 3 recites various markers that are expressed by Wharton's Jelly cells, (*e.g.*, cKit, Oct-4 and alkaline phosphatase) and additionally that the cells are composed of smooth actin-positive myofibroblast-stromal cells. Thus, it appears that the cells express markers that are expressed in hematopoietic cells, ES cells, as well as myofibroblast cells. The breadth of the claims recites "any stem cell", which encompasses pluripotent, multipotent and unipotent cells. Certain embodiments recite that the cells are capable of differentiation into derivatives of endoderm, ectoderm or mesoderm (claim 34), but the disclosure fails to provide sufficient written description for this cell, in the context of the claimed invention. Accordingly, the as-filed disclosure fails to provide a written description for the claimed UCMS cells, and as such, there is no indication that Applicants had possession of the claimed invention. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification, and are not conventional in the art **as of Applicants' effective filing date**. Possession may be shown by actual reduction to practice, clear depiction of the claimed invention in a detailed drawing, or by describing the invention with sufficient, relevant, identifying characteristics (as it relates to the claimed invention as a whole), such that one of skill in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998). In the instant case, stem cells isolated from an umbilical cord matrix lack a written description.

The skilled artisan cannot envision the detailed chemical structure of stem cells that are encompassed by the claims, because the specification fails to provide specific, identifying characteristics of these cells; therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention, and a reference to a potential method of isolating it. See *Fiers v. Revel,* 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991).

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGFs were found to be unpatentable due to lack of written description for that broad class. The specification only provided the bovine sequence.

Applicant is reminded that *Vas-Cath* makes clear that the written description of 35 U.S.C. 112 is severable from its enablement provision [see p. 1115].

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 17-22, 34, 35 and 42are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the limitation "the source of cell" in line 1. There is insufficient antecedent basis for this limitation in the claim. This claim refers back to claim 1, which recites obtaining cells, and fractionating the umbilical cord matrix source of cells. Appropriate correction is required.

Claim 17 recites the limitation "the animal cells" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claims 18-22 similarly recite "the animal cells", which lack antecedent basis. Claim 17 is further unclear, because it recites that the animal cells are "from any amniotic species". It is unclear how this further limits the claim, because only animals that have umbilical cords would have umbilical cord matrix. Appropriate correction is required.

Claim 34 is unclear. The claim recites, "maintaining a karyotype in which all chromosomes characteristic of the human are present ...". It is unclear what the metes and bounds of chromosomes that are "characteristic of the human" encompasses. Aprporpaite correction is required. Claim 35 depends from claim 34.

Claim 35 is unclear. The claim recites ,"capable of" which implies a latent property and the conditions for the latent property must be clearly defined. Therefore, it is unclear if the latent property is ever obtained. Thus, active language would obviate this rejection. Claim 42 is similarly rejected for utilizing the phrase "capable of".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, 34 and 35 rejected under 35 U.S.C. 102(a) as being anticipated by Mitchell *et al.* (Mol. Biol. of the Cell, 12 (Suppl), page 365A, Abstract No. 2006, from the 41st Annual Meeting of the American Society for Cell Biology, December 8-12, 2001, publicly available November 2001).

Mitchell teach the isolation of primitive immortal cells from Wharton's jelly (see first sentence). They identify these stem cells. See last sentence. Although they do not specifically teach that the cells are capable of differentiation into derivatives of endoderm, mesoderm, or ectoderm, these would be an inherent property of the cells. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Accordingly, Mitchell anticipate the claimed invention.

Claims 3, 34, 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Thomson (Science, 282: 1145-1147, November 6, 1998).

Claim 3 is a product by process claim. Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See In re Ludtke, supra. Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. In re Best, Bolton, and Shaw, 195 USPQ 430, 433 (CCPA 1977) citing In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972). Further, see MPEP §2113, "Even though product-by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of

the prior art, the claim is unpatentable even though the prior product was made by a different process."

Claim interpretation: The claims are interpreted as follows: the cells of claim 3 are directed to stem cells isolated form umbilical cord matrix. However, the claim does not require any specific characteristics of the cells, therefore, any stem cells would anticipate this claim. Claims 34-35 are directed to cells "derived from Wharton's Jelly". The term "derived from" is not given patentable weight, because this does not distinguish the claimed cells of claims 34-35, from stem cells known in the art. Additionally, the requirements of the claims, with regard to the karyotype and the differentiation potential (claim 34, parts (a) and (b)) are not exclusive to UCMS cells. Additionally, claim 35 recites that the cells are "capable of" being types, banked or expanded. "Capable of" is a latent term that is not imparted patentable weight, because this is an intended use for the cells, intended used does not impart patentable weight to a product. See MPEP 2111.03:

> Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. In re Casey 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 938, 136 USPQ 458, 459, (CCPA 1963).

Thomson teach human embryonic stem cells that are capable of differentiation into cells of all three embryonic germ layers and have normal karyotypes (see Abstract). Accordingly, Thomson anticipate the claimed invention.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Thaian N. Ton whose telephone number is (571) 272-0736. The Examiner can normally be reached on Monday through Thursday from 7:00 to 5:00 (Eastern Standard Time). Should the Examiner be unavailable, inquiries should be directed to Peter Paras, SPE of Art Unit 1632, at (571) 272-4517. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the Official Fax at (571) 273-8300. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Thaian N. Ton/
Primary Examiner
Art Unit 1632